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EMC

CV 10 3886

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

MAURICE BRIGHAM, individually and on behalf of all others similarly situated,

Plaintiffs,

vs.

DEPUY ORTHOPAEDICS, INC., an Indiana Corporation; JOHNSON & JOHNSON SERVICES, INC., a New Jersey Corporation; and DOES 1-100, inclusive,

CLASS ACTION COMPLAINT FOR:

1) **NEGLIGENCE;**
2) **STRICT PRODUCTS LIABILITY (MANUFACTURING DEFECT);**
3) **STRICT PRODUCTS LIABILITY (DESIGN DEFECT);**
4) **STRICT PRODUCTS LIABILITY (INADEQUATE WARNING);**
5) **STRICT PRODUCTS LIABILITY (FAILURE TO CONFORM TO REPRESENTATIONS);**
6) **STRICT PRODUCTS LIABILITY (FAILURE TO ADEQUATELY TEST);**

Defendants.

7) BREACH OF EXPRESS WARRANTY;
8) BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY;
9) FRAUDULENT CONCEALMENT;
10) INTENTIONAL MISREPRESENTATION;
11) NEGLIGENT MISREPRESENTATION; AND
12) UNLAWFUL, UNFAIR AND FRAUDULENT BUSINESS PRACTICES IN VIOLATION OF CAL. BUS. & PROF. CODE § 17200, *ET SEQ.*

DEMAND FOR JURY TRIAL

Plaintiff MAURICE BRIGHAM ("Plaintiff"), individually and on behalf of a class of similarly situated persons, alleges on information and belief against DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON SERVICES, INC., and DOES 1-100, INCLUSIVE, ("Defendants"), the following:

I.

INTRODUCTION AND SUMMARY OF ACTION

1. For more than two years, Defendants have known that their hip replacement devices – the ASR XL Acetabular System and ASR Hip Resurfacing Platform (collectively, "ASR Hip Implant Devices") – are prone to fail within approximately two years of implantation despite the fact that such hip implant devices are supposed to last more than fifteen years. They have also known that the implant's metal "ball" and "socket" bearings that make up the hip-joint generate metal debris over time from wear and tear that can spread throughout the patient's surrounding bone and tissue. As a result of these defects, patients that have had the devices implanted have endured, or will endure, unnecessary pain and

suffering; debilitating lack of moblity; inflammation causing damage or death to surrounding tissue and bone; and a subsequent more difficult revision surgery to replace the faulty devices giving rise to more debilitation, a prolonged recovery time, and an increased risk of complications and death from surgery. But rather than immediately recalling the ASR Hip Implant Devices upon first receiving notice in 2008 of complaints made to the F.D.A. of the defects discussed above, Defendants continued to aggressively market the ASR Hip Implant Devices, claiming that that they were a safe and effective hip replacement system.

2. Plaintiff's suffering could easily have been prevented. Plaintiff and those like him would not have suffered from unnecessary pain and debilitation, and the need to undergo subsequent revision surgery had Defendants warned the public of the dangers of the ASR Hip Implant Devices in 2007 when dozens of complaints began being made to the F.D.A. regarding the device's failures. Or, even better, had Defendants taken the affirmative step of recalling the ASR Hip Implant Devices at that time, as opposed to more than three years later. But Defendants' recent recall of these devices has come too late for thousands of Americans, including Plaintiff, who will now live with the consequences of these faulty devices for years, if not the rest of their lives. Plaintiff, on behalf of himself and those similarly situated, seeks redress for his injuries.

II.

PARTIES

3. Plaintiff MAURICE BRIGHAM is, and at all times relevant to this Complaint was, a resident of San Bruno, California.

4. Defendant DEPUY ORTHOPAEDICS, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY ORTHOPAEDICS, INC. is and was at all times relevant herein doing business in

and/or having directed its activities at California, and specifically this judicial district.

5. Defendant JOHNSON & JOHNSON SERVICES, INC. is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON SERVICES, INC. is and was at all times relevant herein doing business in and/or having directed its activities at California, and specifically this judicial district.

6. Plaintiff is unaware of the true names and capacities, whether individual, corporate, associate, or otherwise, of defendants DOES 1-100, inclusive, or any of them, and therefore sues these Defendants, and each of them, by such fictitious names. Plaintiff will seek leave of this Court to amend this complaint when the status and identities of these Defendants are ascertained.

7. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each defendant was acting within the course and scope of its agency and was subject to and under the supervision of its co-defendants.

III.

JURISDICTION, VENUE, AND INTRADISTRICT ASSIGNMENT

8. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d)(2)(A). The amount in controversy in this class action is well over $5,000,000, and the class includes residents of potentially all fifty states, plus the District of Columbia. Defendants reside, or have their primary places of business, in Indiana and New Jersey.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a). A substantial portion of the events and omissions giving rise to this lawsuit occurred in this District, and the Court has personal jurisdiction over each of the parties as alleged throughout this Complaint.

10. Assignment is proper in this division under Civil L.R. 3-2 (c) and (d), because a substantial part of the events giving rise to the claims occurred in San Francisco County.

IV.

FACTUAL ALLEGATIONS

A. DEFENDANTS MANUFACTURED AND MARKETED THE ASR HIP IMPLANT DEVICES TO THE PUBLIC, EVEN THOUGH THEY KNEW OR SHOULD HAVE KNOWN OF THE DANGER THAT THE ASR HIP IMPLANT DEVICES POSED TO THE PUBLIC.

11. The ASR Hip Implant Devices were developed in order to reconstruct human hip joints that are diseased due to conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), or fracture. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

12. The ASR XL Acetabular System is made up of three components: the metal femoral stem is inserted inside the femur, the metal femoral head (or ball) connects to the stem and then fits inside the metal acetabulum cup (socket). The ASR Hip Resurfacing Platform has two components: a metal cap is placed over the natural femoral head (or ball) and the acetabulum is replaced with the metal acetabulum cup (socket). Once implanted, these devices are supposed to last for an average of about 15 or more years before requiring replacement.

13. Defendants aggressively marketed the ASR Hip Replacement Devices as having many advantages over other hip replacement or hip resurfacing systems. Defendants described the ASR Hip Replacement Devices as a "high performance hip replacement" and advertised it with pictures of a young woman running on a sandy beach, and a man taking a very aggressive golf swing.

Defendants advertised the ASR Hip Replacement Devices as superior devices as the bone in the hip socket was preserved, the hip replacement was subject to reduced wear, the hip replacement matched the hip's natural anatomy, the surgery only required a small incision, and the device was based on a strong clinical history.

14. Defendants further advertised the ASR Hip Replacement Devices as a superior option "[i]f you have gradually stopped doing the things you enjoy or are adapting your life to cope with reduced mobility hip replacement surgery may be appropriate for you." Defendants further stated that "[f]ortunately, today's advanced techniques and technologies have revolutionized hip replacements. That means more patients can consider treatments at an earlier stage than they could in the past, potentially allowing them to return to their more active lifestyles."

15. Contrary to Defendants' marketing campaigns, for more than two years Defendants have known that the ASR Hip Implant Devices were failing early and therefore causing harm in a high number of patients that received the devices. Specifically, for more than two years, the F.D.A. has been receiving complaints that the devices failed early in some patients due to component loosening, component malalignment, dislocation, and fracture, due to the design of the devices. In addition, reports were received that the implant's "ball" and "socket" that make up the hip-joint – which are both metal bearings – generate metal debris over time from wear which can spread throughout the surrounding bone and tissue and cause severe inflammation and damage. Indeed, since the start of 2008, the F.D.A. has received approximately 400 complaints involving patients in the United States that received the devices, with a substantial number of these patients requiring complicated, expensive and painful revision surgeries with a prolonged recovery time.

16. Notwithstanding these complaints, Defendants neither halted sales of the ASR Hip Implant Devices, nor warned the public until very recently. Instead,

throughout 2008 and 2009 they aggressively marketed the ASR Hip Implant Devices as a safe and effective hip replacement device even though they were on notice of the high number of complaints received by the F.D.A. Only in the last quarter of 2009 did Defendants react by deciding to stop sales of the devices due to decreased demand.

17. However, faced with even more data regarding the dangers of ASR Hip Implant Devices, several months later in late August, 2010, Defendants took the extra step of issuing a voluntary recall of the ASR Hip Implant Devices after "new" data was released confirming the already known dangers of the devices, and corroborating the many complaints received by the F.D.A. from physicians and patients years earlier.

18. The data relied on for the recall includes British studies released in March 2010 showing that metal-on-metal implants, such as the ASR Hip Implant Devices, are potentially dangerous because they can generate large amounts of metallic debris as they wear over time. The metallic debris has been shown to cause severe inflammatory responses in some patients that cause pain in the groin, and death of tissue in the hip joint and loss of surrounding bone, requiring a revision surgery to replace the device soon after implant instead of the 15 or more years artificial hips are supposed to last.

19. The other source is unpublished data from the National Joint Registry (NJR) of England and Wales. The NJR data shows the five year revision rate for the ASR Hip Resurfacing System is approximately 12 percent, and is approximately 13 percent for the ASR XL Acetabular System. Defendants acknowledge that under generally accepted standards, no more than 5 percent of patients should have a revision surgery within five years of implantation. The data released from the NJR shows that the ASR Hip Implant Devices had a revision rate almost three times that of the generally accepted standards.

20. Many surgeons have acknowledged that the culprit for the high number of revision surgeries is due to the design of the acetabulum metal cup which is shallower than other competitor's cups on the market. It is this shallower design which presents a challenge for properly implanting the device which can lead to problems such as loosening of the device, malalignment of the device, and fracture of the device from the bone, all of which can cause severe infection and inflammation in patients.

21. As a result of the issues with the ASR Hip Implant Devices, Plaintiffs have suffered symptoms including pain, swelling, inflammation and damage to surrounding bone and tissue, and partial or complete lack of mobility. As noted above, these symptoms are the result of possible loosening of the implant, where the implant does not stay attached to the bone in the correct position; fracture, where the bone around the implant may have broken; dislocation, where two parts of the implant that move against each other are no longer aligned; or the spread of metal debris from the metal femur head and metal acetabulum cup from rubbing and rotating against each other. For these reasons, revision surgeries have been necessary to remove the faulty ASR Hip Implant Device. However, these revision surgeries present enormous risks to patients because they are technically more difficult than the original implant surgery, the patient is more at risk of complications and death, and the recovery is more prolonged than the original hip replacement surgery.

B. AS A DIRECT AND PROXIMATE RESULT OF DEFENDANTS' FAILURE TO RECALL THE HIP IMPLANT DEVICES EARLIER, PLAINTIFF RECEIVED A HIP IMPLANT DEVICE, AND NOW HAS SUFFERED DEBILITATING PAIN AND THE NEED FOR MULTIPLE REVISION SURGERIES TO REPLACE THE IMPLANT.

22. Plaintiff is a 50 year old male that was employed as an equipment operator. However, he is currently unable to work due to his defective ASR Hip Implant Device.

23. In 2007, Plaintiff underwent hip replacement surgery. An ASR XL Acetabular System was implanted on both sides of his body.

24. Since the surgical implantation of the ASR XL Acetabular Systems, Plaintiff has suffered symptoms including but not limited to pain, swelling, inflammation, infection, and damage to surrounding bone and tissue, and lack of mobility. As a result, in August 2010, Plaintiff required surgery to remove one of the ASR XL Acetabular Systems which was causing his pain and infection. However, due to severe infection of the surrounding tissue and bone, no replacement device has been implanted since the explant surgery. Thus, Plaintiff is currently bedridden and unable to walk unless and until he receives a suitable replacement.

25. Had Plaintiff known that the ASR XL Acetabular System caused pain, swelling, inflammation, infection, and damage to surrounding bone and tissue, problems walking, and the need for a revision surgery to explant the device, Plaintiff would not have elected to have had the ASR XL Acetabular System implanted.

26. As a direct and proximate result of the implantation of ASR XL Acetabular System, Plaintiff has suffered significant harm, including but not limited to physical injury and bodily impairment, debilitating lack of mobility, conscious pain and suffering, and loss of earnings. In addition, because of the faulty nature of the ASR XL Acetabular System, Plaintiff was required to undergo revision surgery to explant the faulty ASR XL Acetabular System. Because of infection to the area, no replacement device was able to be implanted at that time. Thus, once the infection hopefully resolves, Plaintiff will be required to undergo another surgery to implant the replacement device which will present an enormous

risk to Plaintiff because it will be technically more difficult than the original implant surgery, there is an increased risk of complications and death, and the recovery will be more prolonged than the original hip replacement surgery. As a result, Plaintiff will continue to suffer damages in the future.

V.

CLASS ACTION ALLEGATIONS

27. Plaintiff brings this class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b). Plaintiff, who has suffered injury in fact and loss of money or property as a result of the illegal business practices of Defendants, brings the action on behalf of the following Class of persons:

> All persons who underwent hip replacement surgery and had an ASR XL Acetabular System or an ASR Hip Resurfacing Platform, or any component thereof, surgically implanted.

28. Excluded from the Class are Defendants, their employees, officers and agents, and any person who is acting, or has acted, as counsel for any of the Defendants.

29. The Class, which consists of thousands of individuals, is so numerous that joinder is impractical. Moreover, the burden and expense of individual litigation would make it impossible for most Class Members to obtain redress for the wrongs done by Defendants.

30. There are numerous questions of law and fact common to this Class, including but not limited to the following:

a. Whether Defendants manufactured the ASR Hip Implant Devices and marketed them as a safe and effective hip replacement device when they knew or should have known that the ASR Hip Implant Devices were faulty and would give rise to pain, swelling, inflammation and damage to surrounding muscle and tissue, and an inability to walk,

and would require a subsequent revision surgery within less than five years of implantation to replace the device;

b. Whether Defendants were negligent in manufacturing and marketing ASR Hip Implant Devices when they knew or should have known of the danger of that the ASR Hip Implant Devices were faulty and would give rise to pain, swelling, inflammation and damage to surrounding muscle and tissue, and an inability to walk, and would require a subsequent revision surgery within less than five years of implantation to replace the device;

c. Whether Defendants were strictly liable for manufacturing defects in the ASR Hip Implant Devices, including but not limited to defects that resulted in pain, swelling, inflammation and damage to surrounding muscle and tissue, and the inability to walk, and would require a subsequent revision surgery within less than five years of implantation to replace the device;

d. Whether Defendants were strictly liable for design defects in the ASR Hip Implant Devices, including but not limited to defects that resulted in pain, swelling, inflammation and damage to surrounding muscle and tissue, and the inability to walk, and would require a subsequent revision surgery within less than five years of implantation to replace the device;

e. Whether Defendants were strictly liable for failing to warn the public about the dangers of the ASR Hip Implant Devices, including but not limited to the dangers from pain, swelling, inflammation and damage to surrounding muscle and tissue, and the inability to walk, and the need for a subsequent revision surgery within less than five years of implantation to replace the device with an increased risk of complications or death resulting from such revision surgery;

f. Whether Defendants were strictly liable for the failure of the ASR Hip Implant Devices to conform to representations Defendants made about the ASR Hip Implant Devices, including but not limited to Defendants' numerous claims that the ASR Hip Implant Devices were safe and effective hip replacement devices;

g. Whether Defendants were strictly liable for their failure to test the ASR Hip Implant Devices adequately before marketing them;

h. Whether Defendants breached express warranties by manufacturing and marketing the ASR Hip Implant Devices when they knew or should have known about the dangers of the ASR Hip Implant Devices, including but not limited to the dangers from pain, swelling, inflammation and damage to surrounding muscle and tissue, and the inability to walk, and the need for a subsequent revision surgery within less than five years of implantation to replace the device with an increased risk of complications or death resulting from such revision surgery;

i. Whether Defendants breached the implied warranty of merchantability by manufacturing and marketing the ASR Hip Implant Devices when they knew or should have known about the dangers of the ASR Hip Implant Devices, including but not limited to the dangers from pain, swelling, inflammation and damage to surrounding muscle and tissue, and the inability to walk, and the need for a subsequent revision surgery within less than five years of implantation to replace the device with an increased risk of complications or death resulting from such revision surgery;

j. Whether Defendants fraudulently concealed the causal connection between ASR Hip Implant Devices and the dangers of the ASR Hip Implant Devices, including but not limited to the dangers from pain,

swelling, inflammation and damage to surrounding muscle and tissue, and the inability to walk, and the need for a subsequent revision surgery within less than five years of implantation to replace the device with an increased risk of complications or death resulting from such revision surgery;

k. Whether Defendants intentionally misrepresented to the public their knowledge of the effects of the ASR Hip Implant Devices, including but not limited to their knowledge that the ASR Hip Implant Devices could give rise to pain, swelling, inflammation and damage to surrounding muscle and tissue, and the inability to walk, and could require that a patient have a subsequent revision surgery within less than five years of implantation to replace the device with an increased risk of complications or death resulting from such revision surgery;

l. Whether Defendants negligently misrepresented to the public their knowledge of the effects of the ASR Hip Implant Devices, including but not limited to their knowledge that the ASR Hip Implant Devices could give rise to pain, swelling, inflammation and damage to surrounding muscle and tissue, and the inability to walk, and could require that a patient have a subsequent revision surgery within less than five years of implantation to replace the device with an increased risk of complications or death resulting from such revision surgery;

m. Whether Defendants engaged in unlawful, unfair, and fraudulent business practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*, by manufacturing and marketing the ASR Hip Implant Devices when they knew or should have known that the ASR Hip Implant Devices could give rise to pain, swelling, inflammation and damage to surrounding muscle and tissue, and the inability to walk, and could require that a patient have a subsequent revision surgery within less

than five years of implantation to replace the device with an increased risk of complications or death resulting from such revision surgery; and

n. The nature and extent of the damages, injunctive relief, and other equitable relief to which Plaintiffs and other Class Members are entitled.

31. The claims of the named Plaintiff are typical of the claims of the class.

32. Plaintiff will fairly and adequately protect the interests of the class. Plaintiff has retained a law firm renowned for its experience and skill in litigating complex class actions, including pharmaceutical and medical device cases. Indeed, the firm has more than a decade of experience in hip implant replacement cases. In 2001, attorneys from the firm represented hundreds of people who faced a revision surgery to remove defective Inter-Op brand hip replacement implants sold by Sulzer Orthopaedics which resulted in a nationwide settlement of $1.2 billion for patients.

33. Plaintiff has no interests adverse to those of other Class Members.

34. Plaintiff does not expect difficulty in managing this lawsuit as a class action, ascertaining a class, or identifying individual Class Members.

35. Plaintiff reserves the right to amend or modify the class description with greater specificity or to seek certification of subclasses.

VI.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants)

36. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

37. Defendants had a duty to exercise reasonable care in the design, manufacture, testing, marketing and distribution into the stream of commerce of the ASR Hip Implant Devices, including a duty to insure that the ASR Hip Implant Devices did not pose a significantly increased risk of adverse events.

38. Defendants failed to exercise reasonable care in the design, manufacture, testing, marketing and distribution into the stream of commerce of the ASR Hip Implant Devices. Defendants knew or should have known that the ASR Hip Implant Devices could fail early in patients therefore giving rise to pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, and therefore was not safe for use by Plaintiff or Class Members.

39. Despite the fact that Defendants knew or should have known that the ASR Hip Implant Devices could fail early in patients therefore giving rise to pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, Defendants continued to market the ASR Hip Implant Devices as a safe and effective hip replacement systems.

40. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

41. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY (MANUFACTURING DEFECT)

(Against All Defendants)

42. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

43. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices.

44. The ASR Hip Implant Devices that were surgically implanted in Plaintiff and Class Members were defective in their manufacture when they left the hands of Defendants in that they deviated from product specifications, posing a serious risk that they could fail early in patients therefore giving rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

45. As a direct and proximate result of Defendants' placement of the defective ASR Hip Implant Devices into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

46. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY (DESIGN DEFECT)

(Against All Defendants)

47. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

48. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices.

49. The ASR Hip Implant Devices that were surgically implanted in Plaintiff and Class Members were defective in their design when they left the hands of Defendants in that their design was flawed thereby posing a serious risk that the device could fail early in patients therefore giving rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

50. As a direct and proximate result of Defendants' placement of the defective ASR Hip Implant Devices into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

51. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY (INADEQUATE WARNING)

(Against All Defendants)

52. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

53. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices.

54. The ASR Hip Implant Devices placed into the stream of commerce by Defendants were defective due to inadequate warning, because Defendants

knew or should have known that the ASR Hip Implant Devices could fail early in patients therefore give rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, but failed to give consumers adequate warning of such risks. Further, the ASR Hip Implant Devices placed into the stream of commerce by Defendants were surgically implanted in a manner reasonably anticipated by Defendants.

55. As a direct and proximate result of Defendants' placement of the defective ASR Hip Implant Devices into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

56. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

FIFTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY (FAILURE TO CONFORM TO REPRESENTATIONS)

(Against All Defendants)

57. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

58. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices.

59. Defendants made representations to consumers regarding the character or quality of ASR Hip Implant Devices, including but not limited to statements that the ASR Hip Implant Devices were a safe and effective hip

replacement systems. For example, Defendants claimed that the device was based on a "strong clinical history", and that the devices would allow patients to "return to their more active lifestyles."

60. The ASR Hip Implant Devices placed into the stream of commerce by the Defendants were defective in that, when they left the hands of the Defendants, they did not conform to Defendants' representations.

61. Plaintiff justifiably relied upon Defendants' representations regarding the ASR Hip Implant Devices.

62. As a direct and proximate result of Defendants' placement of the defective ASR Hip Implant Devices into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

63. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

SIXTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY (FAILURE TO ADEQUATELY TEST)

(Against All Defendants)

64. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

65. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices.

66. Defendants advised consumers that the ASR Hip Implant Devices were safe and effective hip replacement devices. Defendants failed to adequately test the ASR Hip Implant Devices to ensure that they would not fail early thereby

giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

67. Had Defendants adequately tested the ASR Hip Implant Devices and disclosed the results of those tests to the public, Plaintiff would not have elected to have the ASR Hip Implant Devices surgically implanted.

68. As a direct and proximate result of Defendants' placement of the defective ASR Hip Implant Devices into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

69. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

SEVENTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(Against All Defendants)

70. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

71. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices.

72. Defendants expressly warranted that the ASR Hip Implant Devices were safe and effective hip replacement systems.

73. The ASR Hip Implant Devices placed into the stream of commerce by Defendants did not conform to these express representations because they failed early thereby giving rise to unnecessary physical injury, pain and suffering,

debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

74. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the ASR Hip Implant Devices, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

75. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

EIGHTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(Against All Defendants)

76. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

77. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices.

78. At the time Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices, Defendants knew the use for which the ASR Hip Implant Devices were intended, and impliedly warranted the ASR Hip Implant Devices to be of merchantable quality and safe for such use.

79. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the ASR Hip Implant Devices was of merchantable quality and safe for its intended use.

80. Contrary to Defendants' implied warranties, the ASR Hip Implant Devices was not of merchantable quality or safe for its intended use, because the ASR Hip Implant Devices were unreasonably dangerous as described above.

81. As a direct and proximate result of Defendants' breach of implied warranties regarding the safety and effectiveness of the ASR Hip Implant Devices, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

82. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

NINTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

(Against All Defendants)

83. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

84. Defendants had a duty to inform Plaintiff of all material facts about the ASR Hip Implant Devices based upon their assumption of that responsibility by representing to consumers that the ASR Hip Implant Devices were safe and effective hip replacement systems.

85. Since 2008, Defendants have had actual knowledge that the ASR Hip Implant Devices could fail early thereby giving rise to unnecessary pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

86. The fact that the ASR Hip Implant Devices could fail early thereby giving rise to unnecessary pain and suffering, debilitation, and the need for a

revision surgery to replace the device with the attendant risks of complications and death from such further surgery was, and is, a material fact.

87. Defendants failed to disclose this material fact to consumers, including Plaintiff and Class Members. Instead, Defendants took affirmative steps to prevent physicians and consumers from learning of this material fact, while aggressively marketing the ASR Hip Implant Devices as safe and effective hip replacement systems. This concealment was done with the intent to induce Plaintiff and Class Members to purchase the ASR Hip Implant Devices so that their physicians could surgically implant the devices into Plaintiff and Class Members.

88. In reliance on Defendants' fraudulent concealment of a material fact, Plaintiff and Class Members purchased the ASR Hip Implant Devices so that their physicians could surgically implant the devices into Plaintiff and Class Members. Had Plaintiff and Class Members known that the ASR Hip Implant Devices could fail early thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, they would not have purchased or consumed the ASR Hip Implant Devices.

89. As a result of Defendants' unlawful and fraudulent concealment of the effects of the ASR Hip Implant Devices, the running statute of limitations has been suspended with respect to claims that Plaintiff has brought or could bring. Plaintiff had no knowledge of Defendants' unlawful conduct, or of any of the facts that might have led to the discovery of Defendants' wrongdoing, until shortly before this Class Action Complaint was filed when notice of the recall was sent.

90. As a direct and proximate result of Defendants' fraudulent concealment of the effects of the ASR Hip Implant Devices, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss,

pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

91. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

TENTH CAUSE OF ACTION

INTENTIONAL MISREPRESENTATION

(Against All Defendants)

92. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

93. Since at least 2008, Defendants have had actual knowledge that the ASR Hip Implant Devices could fail early thereby giving rise to unnecessary pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

94. The fact that the ASR Hip Implant Devices could fail early thereby giving rise to unnecessary pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery was, and is, a material fact.

95. Defendants knowingly and intentionally made false representations of material fact to Plaintiff and Class Members, including but not limited to claims that the ASR Hip Implant Devices were safe and effective hip replacement systems. For example, Defendants claimed that the device was based on a "strong clinical history", and that the devices would allow patients to "return to their more active lifestyles."

96. These representations were made with the intent to induce Plaintiff and Class Members to obtain the ASR Hip Implant Devices.

97. In reliance on Defendants' misrepresentations of material fact, Plaintiff and Class Members obtained the ASR Hip Implant Devices. Had Plaintiff and Class Members known that the ASR Hip Implant Devices could fail early thereby giving rise to unnecessary pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, they would not have elected to obtain an ASR Hip Implant Device.

98. As a result of Defendants' intentional misrepresentations regarding the effects of the ASR Hip Implant Device, the running statute of limitations has been suspended with respect to claims that Plaintiff has brought or could bring. Plaintiff had no knowledge of Defendants' unlawful conduct, or of any of the facts that might have led to the discovery of Defendants' wrongdoing, until shortly before this Class Action Complaint was filed when notice of the recall was sent.

99. As a direct and proximate result of Defendants' intentional misrepresentations, including but not limited to claims that the ASR Hip Implant Device was safe for use, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

100. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

ELEVENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(Against All Defendants)

101. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

102. Since at least 2008, Defendants have had actual knowledge that the ASR Hip Implant Devices could fail early thereby giving rise to unnecessary pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

103. The fact that the ASR Hip Implant Devices could fail early thereby giving rise to unnecessary pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery was, and is, a material fact.

104. Defendants recklessly and/or negligently made false representations of material fact to Plaintiff and Class Members, including but not limited to claims that the ASR Hip Implant Devices were safe and effective hip replacement systems. For example, Defendants claimed that the device was based on a "strong clinical history", and that the devices would allow patients to "return to their more active lifestyles."

105. These representations were made with the intent to induce Plaintiff to obtain the ASR Hip Implant Devices.

106. In reliance on Defendants' misrepresentations of material fact, Plaintiff and Class Members obtained the ASR Hip Implant Devices. Had Plaintiff and Class Members known that the ASR Hip Implant Devices could fail early thereby giving rise to unnecessary pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, they would not have elected to obtain an ASR Hip Implant Device.

107. As a result of Defendants' reckless and/or negligent misrepresentations regarding the effects of the ASR Hip Implant Devices, the running statute of limitations has been suspended with respect to claims that Plaintiff has brought or could bring. Plaintiff had no knowledge of Defendants' unlawful conduct, or of any of the facts that might have lead to the discovery of Defendants' wrongdoing, until shortly before this Class Action Complaint was filed when notice of the recall was sent.

108. As a direct and proximate result of Defendants' reckless and/or negligent misrepresentations, including but not limited to claims that the ASR Hip Implant Devices was safe for use, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

109. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

TWELFTH CAUSE OF ACTION

UNLAWFUL, UNFAIR AND FRAUDULENT BUSINESS PRACTICES IN VIOLATION OF CALIFORNIA BUSINESS AND PROFESSIONS CODE § 17200, *ET SEQ*

(Against All Defendants)

110. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

111. California's Unfair Competition Law (UCL) creates a cause of action for those harmed by unfair competition, which includes "any unlawful, unfair or

fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising."

112. Defendants, and each of them, have made numerous misrepresentations to Plaintiff, Class Members, and the general public. Among these misrepresentations are Defendants' claims that the ASR Hip Implant Devices were safe and effective hip replacement systems. For example, Defendants claimed that the device was based on a "strong clinical history", and that the devices would allow patients to "return to their more active lifestyles."

113. Defendants have made numerous misleading omissions, including their failure to disclose to Plaintiff, Class Members, and the general public the results of research showing that that the ASR Hip Implant Devices could fail early thereby giving rise to unnecessary pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery

114. Defendants' business practices relating to the ASR Hip Implant Devices are unlawful because they constitute, *inter alia*, false advertising, intentional misrepresentation and fraudulent concealment. Indeed, Defendants were recently criticized in a warning letter by the F.D.A. for not seeking approval before marketing a hip implant device for an unapproved use.

115. As a direct and proximate result of Defendants' unlawful business practices and false advertising, Plaintiff has suffered significant damages, including but not limited to physical injury and actual loss of money or property, and will continue to suffer such damages in the future.

116. Plaintiff and other Class Members seek an order of this Court awarding damages, restitution, disgorgement, injunctive relief, attorneys' fees and costs, and all other relief allowed under California Business and Professions Code §17200, *et seq.*

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff and the class they represent pray for the following relief:

A. Judgment in favor of Plaintiff and against all Defendants, for damages in such amounts as may be proven at trial;

B. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, loss of consortium, disfigurement, pain and suffering, mental anguish and emotional distress, in such amounts as may be proven at trial;

C. Punitive and/or exemplary damages in such amounts as may be proven at trial;

D. Restitution and disgorgement of all revenue that Defendants have obtained through the manufacture, marketing, sale and administration of the ASR Hip Implant Devices;

E. Attorneys' fees and costs;

F. Pre- and postjudgment interest; and

G. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

Dated: August 30, 2010

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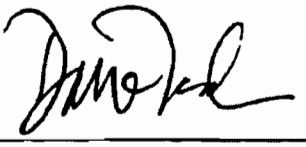
JURY DEMAND

Plaintiffs and the class they represent demand a trial by jury.



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